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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,321	08/04/2006	Rina Aharoni	2819.001	8281
23405 7590 01/27/2009 HESLIN ROTHENBERG FARLEY & MESTI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203				
EXAMINER				
ROBINSON, HOPE A				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/566,321

**Applicant(s)**

AHARONI ET AL.

**Examiner**

HOPE A. ROBINSON

**Art Unit**

1652

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/3/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22, 36 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-10, 18 and 39-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date 9/18/06/7/24/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☒ Other: Notice to Comply

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election without traverse on November 3, 2008 of Group I (claims 1-18, 22 and 36) is acknowledged. Applicant's comments regarding the species election of cyclosporine A and copolymer-1 is acknowledged.

### ***Claim Disposition***

2. Claims 1-22, 36 and 39-41 are pending. Claims 1-2, 4-10, 18 and 39-41 are under examination based on the species election made. Claims 3, 11-17 and 19-22 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. The Amendments filed on January 26, 2006 and November 3, 2008 have been received and entered.

### ***Sequence Compliance***

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicant's attention is directed to the final rule making notice

published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier, see for example, page 23. If these sequences have not been disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See the attached Notice to Comply with the sequence rules.

### ***Specification***

5. The specification is objected to because of the following informalities:  
The specification is objected to because the priority information is not listed on page 1 of the specification, for example, " This application claims priority to ...".  
Correction is required.

### ***Drawing***

6. The drawings filed on January 26, 2006 have been accepted.

***Information Disclosure Statement***

7. The Information Disclosure Statements filed on September 18, 2006 and July 24, 2006 have been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-2, 4-10, 18 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 1 and the dependent claims hereto are indefinite because the claim language is confusing where the claim recites "at least three amino acids each one selected from the at least three of the following groups:

- a) lysine and arginine;
- (b) glutamic acid and aspartic acid;
- (c) alanine, glycine and valine;
- (d) tyrosine, tryptophan and phenylalanine"

because two of the groups have only two amino acids and the "and" recited in each group indicates that they go together as a group and are not to be separated. See also claim 8.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-2, 4-10, 18 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnon et al., (U.S. Patent No. 6,214,791, April 10, 2001) in view Shapiro et al., (US Patent No. 5,668,117, September 16, 1997).

Arnon et al. teach inhibition of graft versus host disease and utilizes Copolymer-1, (also known as glatiramer acetate and marketed under the tradename Copaxone) which comprises the acetate salts of polypeptides containing L-glutamic acid, L-alanine, L-tyrosine and L-lysine (see paragraphs 4 and 5). The average molar fraction of the amino acids is 0.141, 0.427, 0.095 and 0.338, respectively, and the average molecular weight of copolymer-1 is between 4,700 and 11,000 daltons (paragraph 5). Arnon et al. do not teach immunosuppressive drugs, however Shapiro et al. disclose Copolymer-1 and the use of the immunosuppressive drug cyclosporine (see paragraphs 21, 298, 466 and 758). Shapiro et al. establishes that copolymer-1 of MW 14,000 and 23,000 is well known in the art and used in various methods of treatment (column 44, Example 6, lines 47-52).

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole, a method of treating or preventing graft rejection in a subject because Arnon et al. teach the use of copolymer-1 in inhibiting graft versus host disease and Shapiro et al. teach the immunosuppressive drug cyclosporine. One

of ordinary skill in the art would be motivated to combine the teachings of Arnon et al. and Shapiro et al. because Shapiro et al. teach the combined use of copolymer-1 and cyclosporine. Thus, the claimed invention is *prima facie* obvious.

### ***Conclusion***

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

Primary Examiner, Art Unit 1652

